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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,952	10/03/2000	Stephen H. Friend	215538-00401	7342

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EXAMINER

HORLICK, KENNETH R

ART UNIT PAPER NUMBER

1637

DATE MAILED: 08/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/678,952

Applicant(s)

FRIEND ET AL.

Examiner

Kenneth R Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. The examiner has corrected the following informality in the specification:

as active internet links are impermissible, the recited internet addresses have been edited so as to avoid being active.

2. Claims 2, 3, 5-12, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 2, 3, 5-8, 16, and 17 are confusing because it cannot be determined what is encompassed by a "homolog thereof, or an analog thereof" with respect to a gene. Specifically, while this language is discussed briefly on page 6 of the specification, only examples of what might be encompassed are given, and it is unclear what "certain sequences or domains" and "similar functions" refers to.

B) Claims 9-12 are confusing because it cannot be determined what further active step(s) is encompassed by the recited "using" limitation. It is suggested that the intended step be clarified, such as by reciting a "screening" step, for example.

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3. Claims 2, 3, 6, and 9-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While claim 1 is drawn to a method of screening for or identifying a secondary target site such as a *tol* gene, the rejected claims all depend on such a site already being identified and available. Despite the recitation on page 4 of the specification that "...mutations in three recessive yeast genes *tol1*, *tol2*, *tol3* (telomerase overexpression lethal) have been identified that render unviable host cells with an overexpressed telomerase gene *TLC1*...", there is no physical description whatsoever as to what these genes are. Lacking such a description, one of ordinary skill in the art would not find the inventors to be in possession of any such secondary target site or *tol* gene. Consequently, the inventors were clearly not in possession of: the methods of claims 9-12 which require using such a site; the site of claim 13 and the lethal mutations thereof of claim 14; the methods of claims 15-18 which require a drug which interacts with a gene product associated with such a site; the pharmaceutical composition of claims 19 and 20 which require such a drug; the cell of claim 21 which requires such a site; the method of claim 22 which requires a cell having a known *tol* gene; the site of claim 23; the methods of claims 24 and 28 which require use of said drug; nor the pharmaceutical compositions of claims 25-27, 29 and 30 which require said drug. In PTO Tech. Center 1600, such claims as these are sometimes called

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"reach-through", as they encompass subject matter which has not yet been attained by the inventors, but might possibly be attained at some future time with further work/research. Thus, of the pending claims, applicants were only in possession of the screening method by which such sites or tol genes might be identified (claims 1, 4, 5, 7, and 8).

4. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method using yeast cells, does not reasonably provide enablement for any type of cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to carry out the invention commensurate in scope with these claims.

In Ex parte Forman, 230 USPQ 546 (Bd. App. 1986), the Board considered the issue of enablement in molecular biology. In considering these factors: (a) in order to practice the invention, the practitioner must carry out the method using any type of cell; (b) the specification provides guidance with respect to yeast cells; (c) working examples are presented with respect to yeast cells; (d) the invention is directed to screening methods for identifying a secondary target site in relation to an overexpressed telomerase gene using any kind of cells; (e) the prior art teaches genetic screening involving lethal mutations in yeast cells; (f) the level of skill in molecular biology is high; (g) the results of experiments involving various cell types are not predictable; (h) the claims are broadly drawn, reciting any possible cell type. Based on the above analysis, one

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of ordinary skill in the art would be subject to undue experimentation in carrying out the claimed methods using any cells except for yeast.

5. Claims 1-30 are free of the prior art, but are rejected for other reasons. No claims are allowable. Regarding claims 1-12, no prior art has been found teaching or suggesting screening methods comprising: providing cells overexpressing a telomerase activity; effecting a mutation(s) in the genome of the cells at one or more secondary sites; selecting cells having at least one mutation that proves lethal; and determining the site in the genome at which the lethal mutation is located.

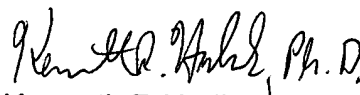
6. Gottschling et al. (US 5,698,686, US 5,916,752, and US 6,387,619) are made of record as references of interest.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Kenneth R Horlick  
Primary Examiner  
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08/14/03